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Premarket Notification
510(k) Summary of Safety and Effectiveness
DRG Reaction Chamber/Safety Tip

Company Information

Doctors Research Group, Inc.
143 Wolcott Road
Wolcott, CT 06716
(p) 203-879-9422
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Contact: Richard Deslauriers, MD

Registration Number: 1226001

Summary Preparation Date

June 20, 2001

Device Information

Trade name:	DRG Reaction Chamber/Safety Tip
Common name:	Electrosurgical Device and Accessories
Classification name:	Electrosurgical Cutting and Coagulation Device and Accessories
Device Classification Panel:	General and Plastic Surgery
Regulation number:	21CFR Part 878.4400
Class:	II
Product Code:	GEI

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Predicate Device

ArthroCare Electrosurgery Systems (ENTec® Surgery System with ENTec™ Plasma Scalpel™, ArthroCare® Orthopedic Electrosurgery System, ArthroCare® Electrosurgery System) (K001936)

Device Description

The DRG Reaction Chamber/Safety Tip is an accessory for Coblation® electrosurgical devices. It creates a sealed chamber during ablation, ensuring continuous liquid supply and suction.

Indications For Use

The DRG Reaction Chamber/Safety Tip is indicated for use as an accessory to standard ablation electrosurgical wands which do not have irrigation and vacuum extraction attached to them. The device provides continuous irrigation and vacuum extraction at the ablation site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Richard K. Deslauriers, M.D.
President
Doctor's Research Group, Inc.
143 Wolcott Road
Wolcott, Connecticut 06716

Re: K012003
Trade/Device Name: DRG Reaction Chamber/Safety Tip
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 28, 2001
Received: November 29, 2001

Dear Dr. Deslauriers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Doctors Research Group, Inc.
143 Wolcott Road
Wolcott, CT 06716
(203) 879-9422

Statement of Indications For Use

510(k) Number (if Known): K012003

Device Name: DRG Reaction Chamber/Safety Tip

Indications for use:

The DRG Reaction Chamber/Safety Tip is indicated for use as an accessory to standard ablation electrosurgical wands which do not have irrigation and vacuum extraction attached to them. The device provides continuous irrigation and vacuum extraction at the ablation site.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDE
Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012003

Prescription Use ✓ **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)